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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,037	10/25/2001	Matthew M. Kumar	44931.1.4	5376

22859 7590 01/21/2004

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EXAMINER

MITCHELL, TEENA KAY

ART UNIT

PAPER NUMBER

3743

DATE MAILED: 01/21/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/037,037	KUMAR ET.AL.
	Examiner	Art Unit
	Teena K Mitchell	3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 25 October 2001.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-33 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-11, 13-17, 19, 20, 23 and 25-31 is/are rejected.
 7) Claim(s) 12, 18, 21, 22, 24 and 32 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 25 October 2001 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) The translation of the foreign language provisional application has been received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____.
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) Other: _____

DETAILED ACTION

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: central aperture 112. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. **Therefore, the plurality of balloon members being inflatable balloon members (only one balloon member is shown not a plurality as claimed) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.**

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11 and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sniadach (2003/0024533) in view of Kondur (4,580,556).

Sniadach in a multi-port mask discloses:

- providing a face mask having a first aperture (12) and
- a second aperture (16),
- the first aperture having a controllably variable inside diameter (15),

- wherein the second aperture is in fluid communication with the breathable gas,
- placing the mask over the face of the patient (Fig. 11);
- supplying the breathable gas to the patient through the second aperture (16);

The difference between Sniadach and claim 1 is Sniadach does not specifically disclose inserting a first shaft member through the first aperture but does disclose that the first port is for airway access, suction access or instrument access (Page 2 column 2 first paragraph after DESCRIPTION).

Kondur in an endotracheal intubation device used with a facemask teaches a first shaft member (42) used for placement of the endotracheal tube.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use any well-known intubation device providing a means for intubation with a first shaft member as the laryngoscope provides visualization for placement of the endotracheal tube. Inasmuch, as Sniadach discloses that the device first port can be used for airway access it would be obvious for one of ordinary skill in the art to use the intubation tube device of Kondur doing so would provide airway access to a patient while allowing visualization during intubation procedure including.

Therefore the steps of inserting a first shaft member through the first aperture would have been obvious by use of the endotracheal device taught by Kondur.

Sniadach discloses forming a seal between the first aperture and the inserted first shaft member (15).

Kondur teaches the use of the device into either an oral or nasal passage of a patient (Col. 3, lines 53-56).

With respect to claim 2, Sniadach discloses wherein the first aperture has an inner wall defining the controllably variable inside diameter (Figs. 12, 13, 15).

With respect to claim 3, Sniadach/Kondur discloses/teaches wherein the first aperture (12) forms as an airtight seal about the inserted first shaft member.

With respect to claim 4, Sniadach discloses supplying the breathable gas at a positive pressure within the mask to the patient (Page 3, [0046]).

With respect to claim 5, Sniadach discloses wherein the breathable gas is enriched oxygen relative to air (Page 2, first column, paragraph [0027]).

With respect to claim 6, Kondur discloses the use of an anesthetic agent (54, 56).

With respect to claim 7, Kondur teaches the use of a laryngoscope used to visualize the trachea (42).

With respect to claim 8, Kondur teaches a second shaft (40) having a lumen there through and the second shaft (40) over the first shaft (42).

With respect to claim 9, Kondur teaches wherein the second shaft is an endotracheal tube (40) and supplying breathable gas through the endotracheal tube.

With respect to removing the mask from the face over the endotracheal tube the mask of Sniadach and Konur is fully capable of such and one of ordinary skill in the art would consider such obvious to remove the mask from the tube as removing the mask after giving anesthetic gas is known in the art while leaving the endotracheal tube in place.

With respect to claim 10, Kondur teaches wherein the endotracheal tube has a proximal end. The step of disconnecting the endotracheal tube from the breathable gas and passing the mask first aperture over the endotracheal tube proximal end would be obvious because such would have resulted from the use of the device.

With respect to claim 11, Kondur discloses wherein the first and second shaft members are advanced together through the first shaft member (40, 42).

With respect to claim 13, Sniadach discloses the claimed invention except for the first aperture being closer to the apex than the second aperture. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the first aperture closer to the apex of the mask than the second aperture, since it has been held that rearranging of parts of an invention involves only routine skill in the art and because regardless of the placement of the first and second apertures on the mask the device would perform equally well. *In re Japikse*, 86 USPQ 70.

With respect to claim 14, inasmuch as the Sniadach discloses that the mask can be used for airway access, suction access or instrument access [0042] it would be obvious to one of ordinary skill in the art at the time the invention was made to use the device for a medical procedure and since placement of a endotracheal tube is a medical procedure and Kondur teaches such it would be obvious to use the device for other medical procedures such as diagnostic or therapeutic.

With respect to claim 15, note rejection of claim 14 above.

With respect to claim 16, Kondur teaches the use of the device in oral and nasal passages (Col. 3, lines 53-56).

With respect to claim 17, Kondur teaches supplying an anesthetic agent (54, 56).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 19, 20, 23, 25, 31, and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Sniadach (2003/0024533).

Sniadach in a mask discloses a mask wall having a generally concave interior shape (Figs. 1-12), the mask wall having a first aperture (12) there through and a second aperture (16), wherein the first aperture (12) has an adjustable inside diameter (15).

With respect to claim 20, Sniadach discloses wherein the first aperture (12) is disposed with a raised lip (13) having an inner wall, wherein the adjustable inside diameter aspect includes an inwardly movable wall (15).

With respect to claim 23, Sniadach discloses wherein the first aperture has an inner wall defined by a plurality of members (Figs. 3, 8, 11, 12), wherein the members have an open position and a closed position, wherein the members are movable between the open and closed position for decreasing the first aperture (12).

With respect to claim 25, Sniadach discloses wherein the plurality of members are iris members (15), which cooperate to decrease the first aperture inside diameter.

With respect to claim 31, Sniadach discloses a facemask wall for extending over the mouth and nose of a patient (Fig. 11); the face mask wall having a first aperture (12) there through and a second aperture (16) there through, wherein the first aperture (12) has a seal (15) therein for providing a controllably variable inside diameter to the first aperture.

With respect to claim 33, Sniadach discloses wherein the first aperture seal (15) includes an adjustable iris.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sniadach (2003/0024533).

With respect to claim 26, Sniadach discloses the claimed invention except for the first aperture being closer to the apex than the second aperture. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the first aperture closer to the apex of the mask than the second aperture, since it has been held that rearranging of parts of an invention involves only routine skill in the art and

because regardless of the placement of the first and second apertures on the mask the device would perform equally well. *In re Japikse*, 86 USPQ 70.

With respect to claim 27, note rejection of claim 26 above.

With respect to claim 28, Sniadach discloses the claimed invention except for the maximum inside diameter of the first aperture being at least about 3/8 inch. At the time the invention was made, it would have been an obvious matter of design consideration to a person of ordinary skill in the art to have the maximum inside diameter of the first aperture to be at least about 3/8 inch because applicant has not disclosed that such diameter is for a particular purpose, or solves any stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with a maximum inside diameter of the first aperture. Inasmuch as different instruments and/or medical tube devices range in size for particular procedures and patients it would be obvious to one of ordinary skill in the art to have the inside diameter of the first aperture at a size for the intended use. Therefore, it would have been an obvious matter of design consideration to modify Sniadach to obtain the invention as specified in claim 28.

With respect to claims 29 and 30, note rejection of claim 28 above.

Allowable Subject Matter

Claims 12, 18, 21, 22, 24, and 32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The overall combination of a face mask with first and second apertures and inflatable balloon to increase and/or decrease the first aperture is neither anticipated nor rendered obvious by the prior art of record.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of art is cited to show facemask with apertures.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (703) 308-4016. The examiner can normally be reached on Monday-Friday during normal business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Teena K Mitchell
Examiner
Art Unit 3743
January 11, 2004



Aaron J. Lewis
Primary Examiner